UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA,

Plaintiff,

v.

Seven 25 pound cases, more or less, of an article of food, labeled in part:

(case)

" *** WHOLE PAPRIKA *** NET WEIGHT: 25 Lb. *** PRODUCT OF PERU *** DISTRIBUTOR: MISKI INC. *** MIAMI, FL 33129 *** "

and

other articles of food in various sizes and types of containers, that are located on the premises of Dominguez Foods of Washington, Inc., 104 5th Street, Zillah, Washington, to which are affixed labels bearing, among other things, the name and address of the manufacturer, packer, or distributor located outside the state of Washington, or otherwise determined to have originated from outside the state of Washington, that are currently held under FDA detention notice DN00002, dated 9/2/11,

Defendants,

And

Dominguez Foods of Washington, Inc.,

Claimant.

No. CV-11-3101-EFS

AMENDED CONSENT DECREE

AMENDED CONSENT DECREE OF CONDEMNATION AND PERMANENT INJUNCTION

On September 29, 2011, the United States of America ("Plaintiff"), by and through its attorneys, filed a Verified Complaint for Forfeiture *In Rem* ("Complaint") against the above-described articles (the "Articles"). The Complaint alleges that the Articles proceeded against are articles of food that are adulterated, within the meaning of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 342(a)(4), while held for sale after shipment in interstate commerce, in that they have been held under insanitary conditions whereby they may have become contaminated with filth. The Complaint further alleges that the Articles are being held illegally within the jurisdiction of this Court and, therefore, are liable for seizure and condemnation under the Act, 21 U.S.C. § 334.

Pursuant to a Warrant of Arrest *In Rem* issued by this Court, the United States Marshal for this District seized the Articles on September 30, 2011. On November 1, 2011, Dominguez Foods of Washington, Inc. ("Claimant"), through its attorneys, intervened and filed a claim to the Articles. No other party has filed a claim to the Articles.

WHEREAS Claimant, having appeared and voluntarily consented to the entry of this Decree without admitting or denying the allegations of the Complaint, before any testimony has been taken, and waiving the filing and service of an amended complaint seeking injunctive relief, and the United States having consented to this Decree: IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

The parties' Stipulated Motion to Amend Consent Decree of Condemnation and Permanent Injunction, **ECF No. 28**, is **GRANTED** as set forth below.

1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334, and personal jurisdiction over all parties to this action. Venue is proper in this district. 28 U.S.C. §§ 1391(b)–(c) & 1395.

2. The Articles are articles of food that are adulterated, within the meaning of 21 U.S.C. § 342(a)(4), while held for sale after shipment in interstate commerce, and are, therefore, condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

3. Claimant affirms that it is the sole owner of the Articles, and that no other person has an interest in the Articles. Claimant shall indemnify and hold the United States harmless should any party or parties hereafter file or seek to file a claim or to intervene in this action and obtain any part of the Articles.

4. Claimant shall pay to the United States all court costs and fees, storage, and other proper expenses, and such further costs for which Claimant is liable pursuant to 21 U.S.C. § 334(e). Claimant shall pay these costs within ten (10) calendar days after receiving notice of such costs from the United States Food and Drug Administration ("FDA"), the United States Marshals Service, and/or the United States Attorney's Office for this District.

5. Within twenty (20) calendar days after the entry of this Decree, Claimant shall execute and file with the clerk of this Court a good and sufficient penal bond ("Bond") with surety in the amount of one hundred thousand dollars ($100,000.00). The Bond shall be in a form acceptable to the clerk of this Court and payable to the United States of America, and conditioned on Claimant abiding by and performing all of the terms and conditions of this Decree and of such further orders and decrees as may be entered in this proceeding.

6. Within twenty (20) calendar days after filing the Bond pursuant to paragraph 5, Claimant, at its own expense, shall retain an individual or individuals (the "Expert") with no personal or financial ties (other than the retention agreement) to Claimant, its officers, or directors, or their families, and who, by reason of education, training, and experience, is qualified to develop and implement a plan to bring the Articles into compliance with the Act. Upon retaining the Expert, Claimant shall inform FDA in writing of the name and

qualifications of said Expert. Claimant shall not commence, or permit any other person to commence, attempting to bring the Articles into compliance with the Act unless and until:

a. the Expert develops and Claimant submits to FDA a written proposal to bring the condemned Articles into compliance with the Act ("Reconditioning Proposal");

b. Claimant receives written approval of the Reconditioning Proposal from FDA; and

c. Claimant receives written authorization from FDA to commence attempting to bring the Articles into compliance with the Act.

7. Following Claimant's payment of costs and posting of the Bond, as required by paragraphs 4 and 5 of this Decree, and following Claimant's receipt of written authorization to commence attempting to bring the Articles into compliance with the Act as described in paragraph 6.c, the United States Marshal, upon receiving notice from the United States Attorney or FDA, shall release the Articles from his custody to the custody of Claimant for the sole purpose of attempting to bring such Articles into compliance pursuant to the Reconditioning Proposal approved pursuant to paragraph 6.b, and under FDA supervision.

8. Within sixty (60) calendar days after receiving written authorization to commence attempting to bring the Articles into compliance with the Act, Claimant shall complete its attempt in accordance with the FDA-approved Reconditioning Proposal, and under FDA supervision. Within ten (10) calendar days after the expiration of this sixty (60) day period, Claimant shall destroy, at its expense and under FDA supervision, all Articles in its custody or control that have not been brought into compliance with the Act, and shall file a notice with the Court certifying that such Articles have been destroyed.

9. If, within ninety (90) days after entry of this decree, Claimant does not avail itself of the opportunity to repossess the Articles, or fails to submit a Reconditioning Proposal that is acceptable to FDA, or if any portion of the condemned Articles remain in the custody of the United States Marshal after expiration of the sixty (60) day time period described in paragraph 8, the United States Marshal shall destroy the articles and make due return to this Court regarding their disposition. Claimant shall bear the costs of storage and destruction that are incurred by the United States pursuant to this paragraph, and shall pay such costs within ten (10) calendar days after receiving an invoice from FDA, the United States Marshals Service, or the United States Attorney's Office.

10. Claimant shall not directly or indirectly cause or permit the shipment, sale, or other disposal of the Articles unless and until FDA has had free access to the Articles, in order to take any samples or perform any tests or examinations that FDA deems necessary, and FDA has released, in writing, the Articles for shipment, sale, or other disposition.

11. Claimant shall at all times, until the Articles have been released pursuant to paragraph 10, retain the Articles intact for examination or inspection by FDA in a place made known to and approved by FDA, and shall maintain the records or other proof necessary to establish the identity of the articles to the satisfaction of FDA.

12. Claimant shall not sell, ship, or dispose of, or permit or cause another person to sell, ship, or dispose of the Articles in a manner contrary to the Act, or contrary to other laws of the United States, or of any State or Territory (as defined in the Act) in which they are disposed of or sold.

13. If Claimant breaches any condition of this Decree, or any subsequent decree or order in this proceeding, it shall, at its own expense, immediately return Articles in Claimant's custody or control that have been released pursuant to paragraphs 7 or 10 to the United States Marshal, or otherwise dispose of them at its

own expense pursuant to further order of this Court. In the event that return of any of the Articles becomes necessary pursuant to this paragraph, Claimant shall be responsible for all costs of storage and disposition that are incurred by the United States.

14. If Claimant fails to abide by and perform all the terms and conditions of this Decree, or of the Bond, or any such further order or decree as may be entered in this proceeding relating to the Articles, then, on motion of the United States in this proceeding, the Bond shall be forfeited in its entirety to the United States and judgment entered thereon in favor of Plaintiff. Any Articles remaining in the custody or control of either Claimant or the United States Marshal shall be destroyed by the United States Marshals Service pursuant to the terms in paragraph 9 of this Decree.

15. The United States Attorney, upon being advised by FDA that all of the Articles have been brought into compliance pursuant to the FDA-approved Reconditioning Proposal or destroyed in compliance with this Decree, and that Claimant has paid all costs as of that date, will file a motion with the Court seeking return of the bond to the Claimant.

16. Within fourteen calendar days after the entry of this Decree, Claimant shall certify in writing to FDA that it has taken corrective actions necessary to render its food storage and processing facility located at 104 5th Street in Zillah, Washington ("Facility") fit for the storage and handling of food. Claimant shall further submit in writing to FDA a detailed list of the corrective actions taken, including documentation sufficient to demonstrate that such actions were taken.

17. Within thirty (30) calendar days after entry of this Decree, Claimant shall certify in writing to FDA that it has prepared and implemented a written sanitation control program (the "Sanitation Control Program"), which shall include adequate methods and controls to ensure that the condition and operation of the Facility do not render food held therein adulterated within the meaning of 21

U.S.C. § 342(a), and comply with the requirements of 21 C.F.R. Part 110. Claimant shall certify in writing that it has assigned responsibility for the Sanitation Control Program to an individual or individuals who, by reason of education, training, and experience in sanitation work, is or are competent to continuously implement the Sanitation Control Program (the "Responsible Individual"). Claimant shall submit in writing to FDA a copy of the Sanitation Control Program and the qualifications of the Responsible Individual.

18. Within thirty (30) calendar days after entry of this Decree, Claimant shall retain at its expense, an independent person or persons (the "Auditor") with no personal or financial ties (other than the retention agreement) to Claimant, its officers, or directors, or their families, who is qualified by education, training, and experience to assess Claimant's compliance with the Act and its implementing regulations, and shall notify FDA in writing of the Auditor's qualifications as soon as the Auditor is retained. Thereafter:

a. The Auditor shall conduct audit inspections of the Facility to evaluate whether Claimant is in compliance with the Act and its implementing regulations. The first such audit inspections shall be conducted not later than six months after the entry of this Decree and not less than once every twelve months thereafter for a period of four years, for a total of not less than five audits.

b. At the conclusion of each audit inspection, the Auditor shall prepare a written report identifying in detail any objectionable conditions at the Facility that could render articles of food held therein adulterated within the meaning of 21 U.S.C. § 342(a)(4). The reports shall be delivered to the Claimant and FDA no later than twenty (20) calendar days after the date each audit inspection is completed.

c. If a report identifies objectionable conditions, Claimant shall, within ten (10) calendar days after receipt of the report, make all necessary corrections. If Claimant concludes that corrective action cannot be achieved within ten (10) calendar days, Claimant shall notify FDA in writing of the basis for its conclusion and a proposed schedule for completing the corrective actions that does not exceed thirty (30) calendar days.

d. Claimant shall make the corrections in accordance with the proposed schedule, unless FDA notifies Claimant in writing that a shorter time frame is required.

e. Within ten (10) calendar days of the required completion date for corrective actions, the Auditor shall review the corrective actions taken by Claimant and report in writing to FDA whether each objectionable condition has been corrected.

19. If at any time after this Decree's entry, Claimant is advised in writing by FDA that conditions in the Facility render articles of food held therein adulterated within the meaning of 21 U.S.C. § 342(a)(4), Claimant shall immediately, upon such notification, discontinue receiving articles of food in interstate commerce and discontinue introducing, delivering for introduction, and causing the introduction or delivery for introduction into interstate commerce articles of food prepared, packaged, or held by Claimant at the Facility, unless and until:

a. FDA, as it deems necessary, inspects the Facility in order to determine whether the Facility and articles of food processed or held therein are in compliance with the Act, its implementing regulations, and this Decree. All costs of such inspection(s) shall be borne by Claimant;

b. Claimant provides FDA access to all records relating to the receipt, storage, and shipment of articles of food, and to the sanitation of the Facility, as FDA deems necessary, and upon FDA's request; and

c. FDA authorizes Claimant in writing to resume receiving and introducing articles of food in interstate commerce.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA.

20. Upon entry of this Decree, Claimant and each and all of its directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (the "Associated Person(s)") who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from causing articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

21. Within ten (10) calendar days after entry of this Decree, Claimant shall post a copy of this Decree in a common area at the Facility and at any other location at which Claimant conducts business, and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

22. Within ten (10) calendar days after entry of this Decree, Claimant shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each of the Associated Person(s). Within thirty (30) calendar days after entry of this Decree, Claimant shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

23. In the event that Claimant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Claimant shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each

time Claimant becomes associated with an additional Associated Person(s), Claimant shall, within ten (10) calendar days, provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this paragraph. Within ten (10) calendar days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Claimant's compliance with this paragraph, Claimant shall provide such information or documentation to FDA.

24. Claimant shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of its business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Dominguez Foods of Washington, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Claimant shall provide a copy of this Decree to any prospective successor or assign at least thirty (30) calendar days prior to any sale or assignment. Claimant shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

25. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Facility, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During inspections of the Facility, FDA shall be permitted to take photographs and make video recordings; to take samples of articles of food and packaging material(s); to examine and copy all records relating to the receiving, manufacturing, preparing, packing, holding, and distributing of any and all articles of food, and to the maintenance and condition of the Facility.

The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

26. Claimant shall reimburse the United States for the costs of supervising Claimant's compliance with the terms of this Decree, including all inspections, examinations, reviews, evaluations, and analyses conducted pursuant to this Decree, at the standard rates prevailing at the time the activities are accomplished. As of the date this Decree is signed by the parties, the rates are $87.57 per hour or fraction thereof per representative for supervision other than laboratory and analytical work; $104.96 per hour or fraction thereof per representative for laboratory and analytical work; and 51 cents per mile for travel expenses for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA's supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

27. Claimant shall abide by the decisions of FDA and its representatives, which shall be final. All decisions specified in this Decree shall be vested in FDA's discretion and, if necessary, shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review by a court of any FDA decision rendered pursuant to this Decree shall be based exclusively upon the written record before FDA at the time of the decision. No discovery shall be taken by either party.

28. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall reference the civil action, be prominently marked "Dominguez Foods of Washington, Inc.," and be addressed to:

District Director
Seattle District Office
U.S. Food and Drug Administration

Department of Health and Human Services
22215 26th Ave SE, Suite 201
Bothell, WA 98021

29. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Claimant shall, in addition to other remedies, reimburse the United States for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, administrative court costs, and any other costs or fees relating to such proceedings.

30. If Claimant has maintained a state of continuous compliance with this Decree, the Act, and its implementing regulations for at least sixty (60) months after entry of this Decree, Claimant may petition FDA for leave to ask this Court to dissolve this Decree. If, at the time of the petition, in FDA's judgment, Claimant has maintained such a state of continuous compliance, FDA will not oppose such a petition, and Claimant may request that this Decree be dissolved.

31. This Court retains jurisdiction over this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED.

Dated this 12th day of July 2012.

s/ Edward F. Shea_____
EDWARD F. SHEA
Senior United States District Judge

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